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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,645	06/20/2001	Vladimir Nikolaevich Pak	U 014605-0	4188

140 7590 03/30/2004

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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/885,645	PAK ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *December 16, 2003, February 2, 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,2 and 4-9* is/are pending in the application.

4a) Of the above claim(s) *1 and 5-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2,4,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *January 21, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Amendment filed December 16, 2003, the IDS filed January 21, 2004 and the Amendment filed February 2, 2004 in response to the Office Action of June 12, 2003 is acknowledged and has been entered. Previously pending claim 3 has been cancelled, claims 1-2, 4-6, 8-9 have been amended and claim 6 has been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention. Claims 2, 4, 8-9 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. It is noted that in the Amendment filed December 16, 2003 that claim 6, formerly a composition claim, was amended from a composition claim to a method claim. The claim now properly belongs in non-elected Group I and has been rejoined to that group.

4. It is noted that Applicant again traverses the restriction requirement.

Applicant reiterates arguments drawn to the use of the claimed complex in affinity chromatography. The arguments have been considered previously but have not been found persuasive for the reasons of record. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

It is noted that Applicant states that Applicant "can not in any way agree to this restriction requirement". It is noted for Applicant's information that MPEP § 1.144 is drawn to petition from requirement for restriction. In particular, after a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition

will not be considered if reconsideration of the requirement was not requested (see MPEP § 1.181).

5. The following rejections are being maintained:

Claim Rejections - 35 USC 112

6. Claims 2, 4 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed June 12, 2003, Section 7, pages 6-12.

Applicant argues that Gura is not relevant because the present complex has been shown in clinical studies to be effective in treatment of tumors and metastasis of tumors of lung, head, neck thorax, liver, breast, thyroid, testicular, ovarian and adrenal cancer and argues that Applicant's have not seen any complications with the use of dextran. Applicant goes on to explain why the concentration of AFP has been chosen and APF's functional properties *in vivo*.

The argument has been considered and appears to be moot since the claims no longer recite an intended use of the claimed complex for the treatment of malignancies, however, in the interests of compact prosecution, if the claims were to be amended to again recite the intended use limitation, the argument would not be found persuasive because no information concerning cancers other than lung cancer has been submitted for Examiner's consideration, and the claims as currently constituted are not drawn to the specific complexes exemplified in the specification. It is noted for Applicant's convenience that it is customary, when disclosing information critical to the breadth of the claims and in answer to issues raised such as that drawn to the immunogenicity of dextran, to submit the information in declaration form under 35 USC 1.131 or 1.132. It is again noted for Applicant's convenience that should such a Declaration be submitted after final

rejection, it would not be considered because there does not appear to be a good and sufficient reason as to why a Declaration was not previously submitted.

Applicant argues that the present complex preparation acts on the cancer cells expressing AFRP, no matter where the cancer and metastases are anatomically located and cites literature wherein AFPR have been described as both endothelial components and epithelial cell surface membrane receptors. The argument has been considered and appears to be moot since the claims no longer recite an intended use of the claimed complex for the treatment of malignancies, however, in the interests of compact prosecution, if the claims were to be amended to again recite the intended use limitation, the argument would not be found persuasive because the intended use of the complex was drawn to the treatment of any malignancy and the claims was not limited to malignancies that express AFPR. Were the claims to be amended to again recite a complex for the treatment of malignancy, the claims would still be rejected in the absence of the additional limitation "wherein said tumors express AFPR". It is again noted for Applicant's convenience that were such an amendment to be submitted after final, the amendment would not be entered because the amendment would be drawn to issues that required additional consideration. Further, in the absence of the submission of the cited references, it is not possible for Examiner to properly consider the suggested support.

Applicant argues that, based on Examples 5 and 6, Applicant's conclude that the complex preparation has positively acted not only on lung cancer but also on spread metastases and therefor it is not justified to limit the possibilities of treatment with the present complex preparation only to treatment of lung. The argument has been considered and appears to be moot since the claims no longer

recite an intended use of the claimed complex for the treatment of malignancies, however, in the interests of compact prosecution, if the claims were to be amended to again recite the intended use limitation, the argument would not be found persuasive because although the Examples clearly show the efficacy of treatment with two specific complexes for lung cancer, the Examples do not enable the broadly claimed invention for the reasons of record.

Applicant states that Applicant does not know if any polyene antibiotic other than those claimed would noncovalently bind to AFP. Applicant states that it is not known how the bond between the antibiotic and AFP is formed and Applicant cannot exclude the aminodeoxyhexose mycosamine group in the formation of the noncovalent bond, more investigation is needed,. However, the claimed antibiotics are stable in complex with AFP. It is noted for Applicant's information that it does not appear that the broadly claimed method has been reduced to practice and that the scope drawn to the antibiotics was clearly proper.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

7. Claims 2, 4, 8-9 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed June 12, 2003, Section 9, pages 12-14.

Applicant argues that, in view of the amendment of claim 2, the rejection is moot. The argument has been considered but has not been found persuasive because the amendment of claim 2 has not addressed the issue drawn to whether or not Applicant was in possession of the claimed invention at the time the invention was made. Although it is certainly clear from Applicant's statements drawn to the polyene antibiotics that Applicant was indeed not in possession of the claimed

invention at the time the invention was made or at the time the response to the first action on the merits was made, no arguments drawn to the fillers are made, thus the rejection based both on the antibiotics and the fillers is maintained. The arguments have been considered but have not been found persuasive and the rejection is maintained.

8. Claim 4 remains rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed June 12, 2003, Section 10, pages 14-15

Applicant argues that documents showing that polyglucin is dextrin 70 and rheopolyglucin is dextran 40 are submitted. The arguments have been considered but have not been found persuasive because the issue raised was not that polyglucin is not dextran 70 or that rheopolyglucin is not dextran 40, but rather that the specification as originally filed does not support the recitations of any of dextran 70, dextran 40, polyglucin or rheopolyglucin and that a change in the spelling of the polymer in the specification and the claims required by a mistake in the specification as originally filed can only be remedied if both the mistake and the meaning intended are obvious from the specification as originally filed. In this case, the altered spelling is not proper and is considered new matter because it is not obvious from the specification as originally filed. Further, it is noted for Applicant's information, that the submission of "evidence" to support the equivalence of polyglucin to dextran 70 and rheopolyglucin to dextran 40, even if relevant to the instant rejection, would not have been found persuasive because the submitted evidence is written in Russian. Examiner does not read Russian and the handwritten information at the top of the pages is not sufficient to support the asserted equivalence.

Further, in an effort to expedite prosecution, Examiner searched both CAS and Derwent in order to establish the equivalence of polyglucin/polyglykine and rheopolyglucin/rheopolyglykine. The search revealed that the registry numbers of polyglucin and polyglykine are different and that the registry numbers of rheopolyglucin and rheopolyglykine are different. Further, a search of equivalence for dextran revealed that although polyglucin and rheopolyglucin are included in the list of terms related to dextran, neither rheopolyglykine nor polyglykine are included in the list (see attached Exhibit 1). Further, a search revealed that neither CAS nor Derwent had any information as to the structure or composition of either rheopolyglykine or polyglykine, thus it is not possible to establish equivalence between rheopolyglykine and rheopolyglucin or polyglucin and polyglykine (see attached Exhibit 2). It is noted that the search validated Examiner's rejection of withdrawn claim 6 wherein Examiner specifically stated, as drawn to polyglykine and rheopolyglykine, that "The specification does not teach how to make the claimed inventive fillers and they appear to be unknown in the art."

Applicant's arguments have not been found persuasive and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC 112

9. Claims 4 is rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The newly added limitations of polyglucin, rheopolyglucin and dextran have no clear support in the specification and the claims as originally filed. A review of the specification did not reveal the disclosure of any of these species. The subject matter claimed in claim 4 broadens the scope of the invention as originally disclosed in the

specification. It is noted that, for applicant's information, for the reasons set forth above no equivalence has been established between polyglucin and polyglykine or rheopolyglucin and rheopolyglykine either in the specification as originally filed or in the art of record. The subject matter claimed in claim 4 broadens the scope of the invention as originally disclosed in the specification.

10. No claims allowed

11. All other objections and rejections recited in the paper mailed June 12, 2003 are hereby withdrawn.

13. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvette Eyler, can be reached at 571-272-0871 The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
March 26, 2004